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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,285	03/23/2001	Hitoshi Nomura	12660-002001	1001

7590 07/01/2005
Fish & Richardson
225 Franklin Street
Boston, MA 02110-2804

EXAMINER

SPECTOR, LORRAINE

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/720,285

Applicant(s)

NOMURA ET AL.

Examiner

Lorraine Spector, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 53-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 60, 61, 63, 64, 69, 70 and 76 is/are allowed.
- 6) ☒ Claim(s) 53-59, 62, 65 and 71-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 52-76 are pending and under consideration.

The objection to the oath or declaration is withdrawn in view of the application data sheet filed 4/19/2005.

The objection to the claims for encompassing non-elected subject matter is withdrawn in view of applicant's amendment.

The new title of the invention is acknowledged.

The rejection of claims under 35 U.S.C. §101 is withdrawn in view of applicant's amendment. However, the rejection under 35 U.S.C. §112, first paragraph is maintained with respect to some of the claims; see below.

New rejections apply to the newly submitted claims.

Priority

In view of the certified translation documents filed 4/19/2005, priority is set at 6/24/1998.

The rejection of claims over U.S. PATENT NO. 6,576,744 is withdrawn in view of the priority document submission. However, upon determination that all claims are allowable, there will be an evaluation made as to whether an interference proceeding is warranted.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 52-59, 62, 65-68, and 71-75 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids encoding the proteins of SEQ ID NO: 1, 3 or 5, or the proteins themselves, or fragments thereof sufficient in length to be used

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for the production of antibodies, does not reasonably provide enablement for variants thereof, including variants encoded by nucleic acids that hybridize with those disclosed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is “undue” include, but are not limited to:

1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The nature of the invention is the proteins of SEQ ID NO: 1, 3 and 5, which applicants have, in the response filed 4/19/2005, pointed out that the specification discloses and enables the use of the claimed compounds for the identification/sorting of hematopoietic cells. That use involves using compounds that *bind* to the disclosed proteins.

It is not accepted practice in the art to use compounds *other* than the compound to which the binding agent is desired to bind, to make or identify said binding agent. Further, the art simply does not recognize such a protocol as being an accepted way to identify a binding agent; the practice in the art is to take the protein in question, without any modifications or changes, and use the protein or fragments of the protein to make and/or isolate agents that bind to it. The art further teaches that the effects of changes in a protein sequence are not predictable with respect to what will or will not bind the resultant molecule, especially in the absence of any information as to what portions of the molecule are important for said binding.

Accordingly, as the claims read on innumerable species that will differ in structure from the disclosed proteins, in unpredictable ways, the specification does not enable use of such variants for the disclosed utility. It would require undue experimentation to make a number of species commensurate in scope with the claims and then determine which such species had the same characteristics as the three claimed proteins with respect to binding activity, and then use such species to isolate binding agents. Accordingly, the Examiner concludes that enablement is not commensurate in scope with the claims.

Claims 52-54, 58, 65, 67, 68, 71 and 72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a new matter rejection.*

The newly introduced claims recite that there may be "one to ten amino acids" deleted, added or substituted. However, there is no basis in the specification as originally filed, either *in ipso verbis*, nor constructively, for the limitation "one to ten". Rather, the specification and originally filed claims recite "one or more" of such changes. Accordingly, the recitation of the limit of "ten" changes constitutes new matter.

Claims 55-57, 59, 66 and 73-75 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record as applied to claims 22-28, 31-34, 37-40, 43-47, 50 and 51 in the office action mailed 10/19/2004 at pages 7-8. *This is a written description rejection.*

Applicant is reminded that in order for two nucleic acids to hybridize under "stringent" conditions, a stretch of only 15-25 nucleotides' identity is required. There is no evidence of conception or possession of a commensurate number of species of nucleic acid that would "hybridize" to the disclosed nucleic acids, nor is there any requirement for retention of any given structure or function. Accordingly, the Examiner maintains this rejection as it applies to the newly introduced claims.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 55-57, 59, 66 and 73-75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims as amended remain indefinite for failing to adequately specify hybridization conditions. Applicants have amended the claims to indicate that stringent conditions "are 65°C , 2x SSC and 0.1% SDS". However, such is insufficient to define stringency. The metes and bounds of what will hybridize are dependent upon the buffer used (which has now been specified), but also, and more importantly, the temperature at which hybridization takes place, and even more importantly, the buffer, time and temperature of the wash step that follows the hybridization step. Thus, the claims remain indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 55-57, 59, 62-66, and 73-75 are rejected under 35 U.S.C. 102(e) as being anticipated by Donaldson et al., U.S. Patent No. 6,057,128, for reasons of record as applied to claims 22-28, 31-34, 37-40, 43-47, 50 and 51 in the previous Office Action at page 9. As hybridization under stringent conditions requires only 15-25 nucleotides' identity, the nucleic

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acids and proteins of Donaldson et al. anticipate the newly introduced claims. It is further noted that Donaldson et al. teach binding assays at columns 4-5.

Conclusion

Claims 60, 61, 63, 64, 69, 70 and 76 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 3:00 P.M. at telephone number 571-272-0893.

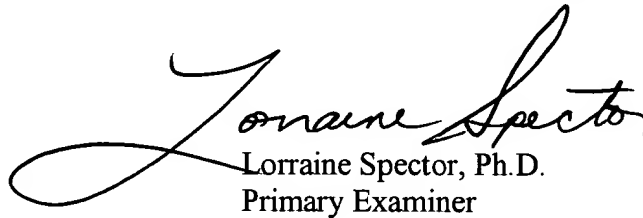
If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's supervisor, Ms. Brenda Brumback, at telephone number 571-272-0961.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). **NOTE:** If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office.

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Official papers filed by fax should be directed to 571-273-8300. Faxed draft or informal communications with the examiner should be directed to **571-273-0893**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lorraine Spector, Ph.D.
Primary Examiner